DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2015

Embolx, Inc.
% Craig Coombs
Coombs Medical Device Consulting, Inc.
1193 Sherman Street
Alameda, California 94501

Re: K142692
Trade/Device Name: Embolx Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: May 28, 2015
Received: May 29, 2015

Dear Craig Coombs,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142692

Device Name
Embolx Occlusion Balloon Catheter

Indications for Use *(Describe)*
The Embolx Occlusion Balloon Catheter is intended for use in the blood vessels of the peripheral vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion for selectively stopping or controlling blood flow. The Embolx Occlusion Balloon Catheter is also intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents into the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	Embolx, Inc. 5760 Arboretum Dr., Los Altos, CA 94024 Tel: 408.888.7792 Fax: 650.968.4069 Contact: Michael Allen, CEO & President Email: mallen@embolx.com
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416 Email: CraigJCoombs@Gmail.com
Device Common Name:	Catheter, Intravascular Occluding, Temporary
Device Classification Number & Name:	21 CFR 870.4450 Vascular Clamp
Device Classification & Product Code:	Class II, MJN
Device Proprietary Name:	Embolx Occlusion Balloon Catheter

Predicate Device Information:

Predicate Device:	Micrus™ Ascent™ Balloon Catheter
Predicate Device Manufacturer:	Codman Neurovascular (a division of Johnson & Johnson Medical Ltd)
Predicate Device Common Name:	Catheter, Intravascular Occluding, Temporary
Predicate Device Premarket Notification #	K103780
Predicate Device Classification:	21 CFR 870.4450
Predicate Device Classification & Product Code:	Class II, MJN

B. Date Summary Prepared

29 May 2015

C. Description of Device

The Embolx Occlusion Balloon Catheter is a coaxial dual lumen device that consists of an occlusion balloon at the distal end with two embedded radiopaque bands to allow for visualization and positioning of the device under fluoroscopic guidance. The proximal hub consists of two ports: one port for use by the guidewire and delivery of fluids and the second port for inflation and deflation of the balloon. The low profile balloon is manufactured of a compliant material that allows ease of insertion and withdrawal from the vasculature and conforms to the vessel wall. The balloon is inflated and deflated with a hand held syringe. The device is supplied sterile by EtO and is intended for single use.

The occlusion catheter has an outside diameter of 2.9F proximally and 2.2F distally. The

occlusion balloon on the distal end can be inflated up to 5mm in diameter and 11mm in length. The usable length of the device is 110cm. The device can withstand an infusion pressure up to 900 psi.

D. Indications for Use

The Embolx Occlusion Balloon Catheter is intended for use in the blood vessels of the peripheral vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion for selectively stopping or controlling blood flow. The Embolx Occlusion Balloon Catheter is also intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents into the peripheral vasculature.

E. Comparison to Predicate Device

The Embolx Occlusion Balloon Catheter is substantially equivalent in intended use, indications for use, technology, design, performance and materials to the predicate device, the Micrus™ Ascent™ Occlusion Balloon Catheter (K103780).

Both devices provide the ability to select specific blood vessels in the peripheral vasculature (of up to 5 mm in diameter) in which temporary control or complete occlusion of blood flow is desired, as well as provide the ability to deliver fluids to the target vessels such as diagnostic and therapeutic agents. The predicate device also has 5mm diameter balloons in its catalogue.

The predicate device is indicated for peripheral and neurovascular use, whereas the application device is only indicated for peripheral use. Since the indication for use of the application device is a subset of the predicate device, the differences do not raise new questions of safety or efficacy.

Both devices are coaxial dual lumen catheters with distal end balloons that are inserted through a guiding catheter via the femoral artery; both devices use guidewires for target vessel selection and have radiopaque markers for visualization under fluoroscopy.

The Embolx Occlusion Balloon Catheter has a working length of 110 cm, whereas the predicate device has a working length of 150 cm due to its indications for use in neurovascular applications as well as peripheral vascular applications. Both devices are single use only and ethylene oxide sterilized.

Both devices are nearly the same outside diameter. The predicate catheter is 2.9Fr in outside diameter and the application device ranges from 2.9Fr on the proximal end to 2.2Fr on the distal end. The predicate device can accommodate guidewires that are 0.014" in diameter or smaller, whereas the application device can accommodate guidewires that are 0.016" or smaller in diameter.

Other than working length of the catheter, all other significant aspects of the Embolx Occlusion Balloon Catheter and the predicate device are comparable. The testing described below demonstrates that the minor differences in the devices do not raise any unresolved issues of safety or efficacy.

Embolx concludes that the application and predicate devices are substantially equivalent.

F. Summary of Supporting Data

Where appropriate, all testing was conducted on sterilized and aged test articles. Substantial equivalence was demonstrated through the following non-clinical testing:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Complement Activation (C3a and Sc5b-9)
- Hemocompatibility
    - ASTM Hemolysis (direct and indirect)
    - In-vivo Thrombogenicity (canine)
    - Partial Thromboplastin Time (PTT)
    - Prothrombin Time Assay (PT)
- Pyrogenicity (LAL)
- Material-mediated Pyrogencity
- Appropriate Sterilization and Packaging Testing
    - Sterilization validation
    - Packaging seal integrity
    - Dye penetration
    - Transit testing
- Dimensional Verification
- Balloon Prep, Deployment, & Retraction (simulated use)
- Balloon Rated Burst Volume
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation/Deflation Time
- Balloon Position Test
- Catheter Bond Strength (tensile testing)
- Tip Pull Strength (tensile testing)
- Flexibility & Kink Test
- Torque Strength
- Radiopacity
- Coating Integrity
- Catheter Body Burst Test
- Catheter body Leakage test
- Contrast Media Flow Rate
- Corrosion Resistance

Embolx concludes that these nonclinical tests demonstrate that the Embolx Occlusion Balloon Catheter is as safe, as effective, and performs as well as or better than the predicate device.